UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

JUN 25 2009

MEMORANDUM

SUBJECT: BPPD Review of Monsanto's Response to SmartStax PIP DNA Analysis
(Decision No: 394799; DP Barcode: 366515).

FROM: John L. Kough, Ph.D. Senior Scientitst
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

TO: Mike Mendelsohn, Senior Regulatory Action Leader
Microbial Pesticides Branch, Biopesticides and
Pollution Prevention Division (7511P)

ACTION REQUESTED: Review the information supplied by Monsanto to address deficiencies identified in the March 13, 2009 memorandum on DNA analysis and protein expression.

BACKGROUND:
The SmartStax PIP product combines several traits to control lepidopteran and coleopteran pest of corn. These traits are Cry1F (EPA reg. no. 68467-2), Cry34ab1 and Cry35Ab1 (EPA reg. no. 68467-5) from Dow AgroScience and Cry2Ab2, Cry1A.105 (EPA reg. no. 524-575) and Cry3Bb1 (EPA reg.no. 524-551) from Monsanto Company. These two combination PIP products have been traditionally bred together to provide higher levels of pest control and decrease the likelihood of developing pest insect resistance.

CONCLUSION: The map of plasmid PHP17661 correctly accounts for the size of the band appearing in the control lane of the Cry34Ab1 *Sac* I digest. The plasmid map and explanation of existing herbicide labels for glyphosate and glufosinate address the discrepancies identified in original submission.

CONTAINS FIFRA CONFIDENTIAL BUSINESS INFORMATION

DATA REVIEW RECORD

Active Ingredient: Cry1a.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry 34ab1, Cry35Ab1
Product Name: SmartStax corn
Company Name: Monsanto Company and Dow AgroSciences
Decision No.: 394799
DP Barcode: 366515
Submission No: 848680

SUMMARY OF INFORMATION SUBMITTED:

In a letter dated April 9, 2009 from J. Austin Burns, Ph.D. representing Monsanto Company responded to the comments in a memorandum about changes in herbicide usage and discrepancies in the southern blot analysis for Cry34Ab1. The provided map of plasmid PHP17661 clarifies that the expected fragment size was 9495 bp for the *Sac* I digest for Cry34Ab1 as seen on the southern blot (lane 2, figure #7, p28 of MRID 47444904). This is more appropriate than the 13,414 bp *Sac* I fragment suggested from the plasmid map of PHP17662. The map of plasmid PHP17661 is attached.

The issue of herbicide use was addressed by the statement that there are no anticipated amendments to the glyphosate or glufosinate labels to allow a mixed use. The letter states that the only anticipated use would be a sequential use as allowed for in the existing registrations. The most likely use would be a rescue use to control weed escapes.

6/25/09 BPPD Review of Registrant's Response to Smartstax

Page 3 is not included in this copy. PIP DNA Analysis

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

__✓__ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.

_____ Attorney-Client Privilege.

__✓__ Claimed Confidential by submitter upon submission to the Agency.

_____ Internal Deliberative Information.

* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.